DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

August 3, 2001

WARNING LETTER
CHI-41-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dana Belisle, President,
Coral Blood Services
300 Professional Drive
Scarsborough, ME 040784

Dear Mr. Belisle:

An inspection of your unlicensed donor center located at 2300 Children's Plaza, Chicago, IL, was conducted on July 11 & 18, 2001. The inspection revealed deviations from Title 21, Code of Federal Regulations, Parts 600-680. These deviations cause the blood products prepared at this location to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). At the conclusion of the inspection, Investigator Jeanne M. Morris issued the Form FDA 483, List of Inspectional Observations, to Sheila M. Maillet, Director, Regulatory Affairs and Quality Assurance. The deviations found include, but are not limited to, the following:

- Whole Blood, which is NOT used to prepare platelets, is stored at room temperature for at least the duration of the collection day. [21 CFR 640.4(h)]

- Failure of written Standard Operating Procedures (SOPs) to include descriptions of the storage conditions for units of Whole Blood immediately after collection. [21 CFR 606.100 (b)(11)]

- Red Blood Cells may be separated from Whole Blood several days after collection. This processing step is completed at room temperature, causing the temperature of the blood to increase during processing. [21 CFR 640.16(a)]

- Review of Donor Registration and Screening Forms revealed not all questions were answered, and insufficient information was elicited from donors to determine if they had traveled to areas at risk for malaria. Despite these deficiencies, products were collected and issued for transfusion. [21 CFR 640.3(a)]

- The "Donor Cumulative Record" failed to contain complete information, and in at least 2 cases, shortened the donor's eligibility date by several weeks. [21 606.160(b)]

In addition to discussing the above identified observations with Ms. Maillet, Investigator Morris discussed the fact that she observed the donor center configuration at the facility and she saw that a single table was shared between two donor beds. Investigator Morris told Ms. Maillet that she observed a phlebotomy and noted that donor's paperwork and pilot tubes were labeled at the beside, on the table between the beds. Our concern is that if both donor beds were occupied at the same time, and the same table was used to prepare the paperwork, the unit and pilot tube labels could easily be interchanged possibly causing the viral marker test results to be linked to the wrong donor/unit.

Neither this letter nor the FDA-483, List of Inspectional Observations, issued at the conclusion of the inspection is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the regulations. A copy of the FDA 483 was faxed to you on July 20, 2001, during the telephone conversation you held with District Director Raymond V. Mlecko and other Chicago District officials.

You should take prompt action to correct these deviations. Failure to implement corrections may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. During your July 20th telephone conversation with Mr. Mlecko, you discussed the corrective steps you were taking or planned to take. Please provide the status of these actions in your response. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measure will be implemented. Your reply should be sent to the attention of George F. Bailey, Compliance Officer, at the above listed address.

Sincerely,

\s\
Raymond V. Mlecko
District Director